

REMARKS

Favorable reconsideration of the subject application is respectfully considered in view of the above amendments and the following remarks. Following the amendments, claims 23-46 are pending in the application, with claims 23, 25, 27, 29, 31, 33, 35, 37, 39, 41, 43 and 45 being in independent format.

The specification has been amended to update the reference to related applications and to correct a minor typographical error. Claims 8 and 9 have been cancelled from the application and rewritten as newly added claims 23-34. Specifically, independent claims 23, 25, 27, 29, 31 and 33 recite methods for detecting prostate cancer in a patient, comprising obtaining a biological sample from the patient and contacting the sample with at least two oligonucleotide primers, wherein at least one of the oligonucleotides is specific for a DNA molecule comprising one or more of the elected DNA sequences, and wherein the biological sample is either blood or serum. Newly added claims 35-46 are drawn to methods for detecting the presence of a DNA molecule comprising one of the elected DNA sequences in a biological sample, the method comprising contacting the sample with an oligonucleotide primer that is specific for the DNA molecule. It is urged that support for all the above amendments may be found throughout the specification as originally filed and that none of the amendments constitute new matter.

The pending claims stand rejected under 35 USC §112, second paragraph, as being indefinite. Specifically, the Examiner objected to the terms “immunogenic portions” and “variants thereof”. While Applicants do not acquiesce in this rejection, these terms have been omitted from the newly added claims in order to expedite their allowance. The Examiner has further noted that SEQ ID NO: 172 is an amino acid sequence, not a DNA sequence. This sequence has been omitted from the newly added claims.

It is submitted that, following the above amendments, the pending claims fully satisfy the requirements of 35 USC §112, second paragraph, and that this rejection may be properly withdrawn.

The claims stand rejected under 35 USC §112, first paragraph, as lacking an enabling disclosure. Specifically, the Examiner states that the specification “does not reasonably provide enablement for detection of prostate cancer”. This rejection is respectfully traversed.

In response to the Restriction Requirement, Applicants elected the species of SEQ ID NO: 110, 111, 115, 173-175, 177, 223 and 224. As noted in the specification at page 27, lines 11-12, SEQ ID NO: 110 and 111 are the full-length cDNA sequences for the antigens L1-12 and N1-1862 (also referred to as P501S and P503S), respectively. SEQ ID NO: 115 is a partial

cDNA sequence for the antigen P89. SEQ ID NO: 173-175 and 177 represent splice variant cDNA sequences of an antigen referred to as P703P. SEQ ID NO: 223 and 224 represent partial cDNA sequences of two antigens referred to as P509S and P510S, respectively.

Following the above amendments, pending claims 35-46 are drawn to methods for detecting the presence of a DNA molecule comprising one of the elected DNA sequences in a biological sample, both methods involving contacting a biological sample with an oligonucleotide primer specific for one of the elected DNA sequences in a polymerase chain reaction (PCR). Applicants note that the Examiner has stated that the specification is "enabling for detecting nucleic acids comprising SEQ ID NOS: 110, 111, 115, 173-177, 223 or 224".

The remaining claims (claims 23-34) are drawn to methods of detecting prostate cancer in a patient by obtaining a biological sample from the patient and contacting the sample with an oligonucleotide primer specific for one of the elected DNA sequences in a polymerase chain reaction (PCR), wherein the biological sample is either blood or serum.

As noted in the specification on page 29, lines 14-19, the antigens P509S and P510S were found to be over-expressed in prostate tumor and normal prostate compared to all other normal tissues tested as determined by microarray technology. Similarly, using RT-PCR, Northern analysis and micro-array technology, L1-12 and N1-1862 were found to be expressed at significantly higher levels in prostate tumor and normal prostate compared to other normal tissues tested (see Example 2, page 29, line 26-page 32, line 2). It is thus submitted that one of skill in the art to which the present invention pertains would reasonably expect an oligonucleotide primer specific for one of the elected sequences to be effective in the detection of prostate cells in a blood or serum sample by means of PCR.

It is well known to those of skill in the art that prostate cells are not found in the blood of normal healthy individuals. However, when an individual is afflicted with prostate cancer, the prostate tumor is able to break through the membrane surrounding the prostate thereby permitting both normal prostate and prostate tumor cells to enter the capillaries and get into the blood stream. Thus the presence of either normal prostate or prostate tumor cells in the blood or serum of an individual is indicative of the presence of prostate cancer. Similarly, the presence of either normal prostate or prostate tumor cells in the blood or serum after removal of the prostate in a patient previously diagnosed with prostate cancer is indicative of the presence of residual disease. It is thus urged that the detection of a DNA molecule comprising a sequence of SEQ ID NO: 110, 111, 115, 173-175, 177, 223 or 224 in the blood or serum of an individual would be indicative of the presence of prostate cancer.

Applicants submit that one of skill in the art to which the present invention pertains, on being provided with the instant specification, would clearly be able to practice the presently claimed methods, and that the rejection of the claims under 35 USC §112, first paragraph, may be properly withdrawn.

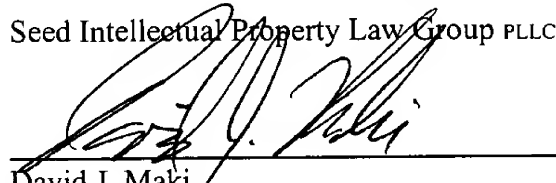
The claims stand rejected under 35 USC §102(e) as being anticipated by Bandman *et al.* (U.S. Patent 5,786,148). Specifically, the Examiner states that Bandman *et al.* teach nucleic acid sequences that encode an immunogenic portion or variant of the polypeptides encoded by a SEQ ID NO: 173-175 and 177. Following the above amendments, none of the pending claims recite immunogenic portions or variants of SEQ ID NO: 173-175 and 177. It is urged that Bandman *et al.* neither teach nor suggest the sequences of SEQ ID NO: 173-175 and 177, nor do they teach or suggest the presently claimed methods of use of these sequences. Applicants thus submit that the present rejection of the claims under 35 USC §102(e) may be properly withdrawn.

Favorable reconsideration and allowance of the amended claims is respectfully requested.

Respectfully submitted,

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Enclosures:

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Petition for an Extension of Time (+ 2 copies)

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